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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,759	09/08/2003	David Lewis	48924-01030	1172

34013 7590 07/27/2006

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,759

Applicant(s)

LEWIS ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of Amendments and Remarks filed on 05/09/06. No claims amended, added or cancelled. Accordingly claims 1-23 remain pending. Applicant's submission of 2 Terminal Disclaimers on 05/09/06 have overcome the Double patenting rejections and thus the said rejections are **withdrawn**.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Lasserre et al (6,296,156).

Wu teaches a medicinal aerosol steroid formulation product with enhanced stability. The steroid is a 20-ketosteroid having an OH group at the C-17 or C-21 position and the aerosol container has a non-metal interior surface which has been found to reduce chemical degradation of such steroids (see abstract). Wu also discloses that steroids, especially 20-ketosteroids, are subject to enhanced chemical degradation, when stored in contact with a metal container (particularly the metal oxide e.g.,  $Al_2O_3$  layer that forms on the interior surface of the container) (see page 3). The preferred 20-ketosteroids include budesonide, triamcinolone acetonide, dexamethasone and betamethasone. The most preferred type of container is a conventional aluminum (or aluminum alloy) aerosol canister, the interior surface of which is coated with an inert material, such as spray-coated, baked epoxy-phenolic lacquer. The internal surfaces of

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metal valve components in contact with the formulation are similarly coated with an inert material. Another preferred coating for the inside of the container is perfluoroethylenepropylene (FEP). The coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier and the inside and outside of the valve stem (see page 4). Wu lacks specific disclosure on the rolled neck canister.

Lasserre et al teaches a mounting device for mounting a valve on a container and a dispenser containing a product under pressure fitted with such a mounting device. The inner surface of the cup which comes in contact with the product is coated with a lacquer or some other inert thermoplastic layer (col. 1, lines 63-65). The container containing a product, particularly a liquid, placed under pressure by a conventional propellant, to be dispensed by actuation of the dispensing valve. The open end of the container is formed by a neck, the said neck having a profile capable of engaging with a portion formed on the said external first mounting means. The neck of the container may be rolled outwards with respect to the central axis of the container or alternatively may be rolled inwards with respect to the axis of the container. The neck of the container has an edge bent towards the central axis of the container (col. 4, lines 1-34). The container may be a one-piece aluminum can. The cup is made of plastic, such as polyacetal (col. 4, lines 63-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation, to have looked in the art for a more specific device with rolled neck to use with the said formulations, as taught by Lasserre with a reasonable expectations of successfully preparing a stable steroid formulation.

### ***Response to Arguments***

Applicant's arguments filed 05/09/06 have been fully considered but they are not persuasive.

Applicant's main argument is that Wu and Lasserre are solving the problem of chemical stability of the formulation differently than the instant invention is. This is not persuasive. Firstly claims 1-16 are drawn to a product comprising a solution formulation and an aerosol canister. It has been shown that these limitations have been met by the cited prior art. Wu is clearly teaching the formulation and a canister with a gasket to prevent contact of the formulation with metal component (see page 6, lines 20-26). Secondly, when WU teaches that formulation should be kept away from the metal surfaces of the canister, it includes the edges of the neck too. Thus the combined references teach a method of providing a stable formulation.

Applicant argues that WU is solving the stability of the solution by coating the inside of the canister. This is correct but not persuasive, because the instant claims also require part or all of the internal surfaces be coated by inert material. Also the figures of

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the canister of WU show that the neck is rolled and that the gasket keeps the formulation inside the canister and away from contact with the metal part. This is exactly what the instant Application is claiming.

Applicant argues that Lasserre does not address the problem related to stability of the solution. Applicant continues that "In fact, Lasserre's containers which are mainly directed the cosmetic field are preferably made of one-piece aluminum can or glass. These materials, if not specially treated or coated, would accelerate the degradation of medical formulation in the container". This is not persuasive. 1) Instant claims do not exclude a one-piece container. Typically most canisters are one-piece. 2) As mentioned above, claims of the instant application also require a coating of the internal surface of the canister. In fact, Lasserre, WU and the present Application all require and teach internal coating of the canister, because it is clear that this step provides for stability of the formulation.

Applicant argues that "Lasserre discloses that the neck of the container maybe rolled outwards or inwards with respect to the axis of the container..... Lasserre in no way discloses or suggests to utilize containers with rolled necks to improve the chemical stability of an aerosol formulation contained in the dispenser or even to prevent the corrosion of the dispenser valve by the product to be dispensed". This is not persuasive because 1) the instant claims do not specify rolled inwards or outwards. 2) While Lasserre teaches that the neck may be rolled inwards or outwards, the figures show a neck rolled outwards and a plastic cup that is clearly sealing the formulation inside the canister and a valve system. Lasserre reads "A plastic mounting device has the

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following advantage: it has **no portion** likely to be exposed to any **corrosion** by the product" (see col. 6, lines 33-45). Although Lasserre et al do not expressly disclose that the rolled neck helps stability of the formulation, it is clear that stability and shelf life of the product is their goal and that their disclosed canister has all the parts and limitations of the canister disclosed by the present application.

All claims are obvious over the cited prior art. No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

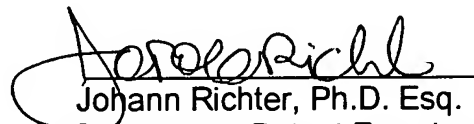
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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July 20, 2006

  
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